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EXAMINER

BOYD, JENNIFER A

ART UNIT

PAPER NUMBER

1771

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,755

Applicant(s)

TOPOLKARAEV ET AL.

Examiner

Jennifer A. Boyd

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The Applicant's Amendments and Accompanying Remarks, filed July 25, 2005, have been entered and have been carefully considered. Claims 1 and 21 are amended, claims 15 – 16 are cancelled and claims 1 – 14 and 17 – 21 are pending. In view of Applicant's Terminal Disclaimer stating common ownership of Tsai et al. (US 6,838,403), the Examiner withdraws the rejection as detailed in paragraph 5 of the Office Action dated April 29, 2005. In view of Applicant's amendments to claims 1 and 21 requiring that the film is laminated to a nonwoven web, the Examiner has amended the previously applied rejections below. The invention as currently claimed is unpatentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1 – 3, 5 – 6, 8 – 9 and 17 – 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5,851,937). The details of the rejection can be found in paragraph 3 of the Office Action dated April 29, 2005. The rejection is maintained.

Independent claims 1 and 21 have been amended to include the limitations of previously found claim 16. Wu teaches that the film may be laminated to a non-woven material (column 2, lines 15 – 30).

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4. Claims 1 – 3, 5 – 6, 8 – 14 and 17 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5,200,247) in view of Wu (US 5,851,937).

Wu '247 is directed to a biodegradable film suitable for diaper backsheets, sanitary napkins and pads and other medical packaging and garment applications (column 2, lines 50 – 55).

As to claims 1 and 21, Wu '247 teaches a biodegradable film comprising a blend of an alkanoyl polymer and a polyvinyl alcohol polymer (column 1, lines 65 – 69). Wu '247 teaches in Examples 1 – 6 the use of blended polycaprolactone and polyvinyl alcohol to form the film (column 7, lines 59 – 65). The Examiner equates the polycaprolactone to Applicant's "biodegradable polymer"; it is indicated on page 6 of Applicant's Specification that polycaprolactone is a biodegradable polymer. The Examiner equates the polyvinyl alcohol to Applicant's "water soluble polymer"; it is indicated on page 6 of Applicant's Specification that polyvinyl alcohol is a water soluble polymer. Wu '247 teaches that the films in Examples 1 – 6 were mechanically stretched (column 8, lines 1 – 3).

As to claims 5 and 6, Wu '247 teaches in Examples 1 – 6 the use of blended polycaprolactone and polyvinyl alcohol to form the film (column 7, lines 59 – 65). The Examiner equates the polycaprolactone to Applicant's "biodegradable polymer" and the polyvinyl alcohol to Applicant's "water soluble polymer".

As to claims 10 – 13, Wu '247 teaches that the film preferably comprises 10 – 25% polyvinyl alcohol, or "water soluble polymer", and 90 – 75% thermoplastic dialkanoyl or oxyalkanoyl polymer, or "biodegradable polymer" (column 2, lines 15 – 25).

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As to claim 14, Wu '247 teaches that the film has a thickness between 1 – 25 mils (column 4, lines 40 – 50).

As to claim 17, Wu '247 teaches that the composite is suitable for diaper backsheets, sanitary napkins and pads and other medical packaging and garment applications (column 2, lines 50 – 55).

As to claim 18, Wu '247 teaches that the composite is biodegradable (Title) so it is implied that it is used in disposable applications.

Wu '247 fails to teach that the film can be laminated to a nonwoven web.

Wu '937 teaches a film comprising polycaprolactone blended with polyvinyl alcohol (PVA) (column 2, lines 35 – 50). Wu teaches that the composite can be incrementally stretched to create a film with micropores or microvoids (column 3, lines 65 – 69 and column 4, lines 1 – 2). The microvoid formation caused breathability in the biodegradable and/or compostable thermoplastic film. The breathability allows air and moisture vapor to breathe or pass through the film. Further, the increased surface area provided by stretching the film accordingly enhances the biodegradability and/or compostability of the film (column 4, lines 1 – 10). Wu teaches that the film may be laminated to one or more nonwoven webs (column 2, lines 15 – 30) to create a laminate having a soft cloth-like feel suitable for hygiene fabrics, medical fabrics and protective ground coverings (column 2, lines 1 – 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to laminate a nonwoven web as suggested by Wu '937 to the film of Wu '247

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motivated by the desire to create a soft fabric suitable for various end uses such as hygiene fabrics and medical fabrics.

As to claims 1 – 3 and 19, Wu '247 in view of Wu '937 teaches the claimed invention but fails to disclose claimed water vapor transmission rate of greater than 2500 g/m²/24 hours as required by claim 1, water vapor transmission rate of greater than 3000 g/m²/24 hours as required by claim 2, water vapor transmission rate of greater than 3500 g/m²/24 hours as required by claim 3 and the film is stretched from about 100 – 500 percent of its original length as required by claim 19. It should be noted that water vapor transmission rate and percentage of stretching are result effective variable. Wu '247 teaches that micropores or microvoids may be formed in the film by stretching at room temperature. The stretched areas weaken the film to further enhance its degradation while maintaining film water impermeability (column 2, lines 25 – 50). As the film is stretched to a greater extent, more microvoids form and as a result the film has a higher water vapor transmission rate and enhanced biodegradability. If the film is stretched too much, the film will become too weak and break. It would have been obvious to one having ordinary skill in the art at the time the invention was made to stretch the film to a certain level to create a film with a vapor transmission rate of greater than 2500 g/m²/24 hours as required by claim 1, water vapor transmission rate of greater than 3000 g/m²/24 hours as required by claim 2, water vapor transmission rate of greater than 3500 g/m²/24 hours as required by claim 3 and the film is stretched from about 100 – 500 percent of its original length as required by claim 19 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present

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invention, one would have been motivated to stretch a film to an optimal level to create film with a high water vapor transmission rate making it suitable for disposable products.

As to claims 8 – 9 and 20, although Wu '247 in view of Wu '937 does not explicitly teach the claimed elongation at break of greater than about 100% as required by claim 8, elongation at break of greater than about 200% as required by claim 9 and elongation at break of about 350% or greater as required by claim 20, it is reasonable to presume that said properties are inherent. Support for said presumption is found in the use of like materials (i.e. a stretched biodegradable film comprising a composition of a blended mixture of a biodegradable polymer and a water soluble polymer having a water vapor transmission rate of greater than 3500 g/m²/24 hours), which would result in the claimed property. The burden is upon the Applicant to prove otherwise. In addition, the presently claimed properties of elongation at break of greater than about 100% as required by claim 8, elongation at break of greater than about 200% as required by claim 9 and elongation at break of about 350% or greater as required by claim 20 would obviously have been present once the Wu '247 in view of Wu '937 product is provided.

5. Claims 1 – 14 and 17 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (US 6,432,547) in view of Noda et al. (US 6,808,795) and further in view of Wu (US 5,851,937).

Kroll is directed to a breathable film layer composition (Title) useful in applications such as disposable articles such as disposable diapers, feminine napkins and medical devices and dressings (column 1, lines 10 – 17).

As to claims 1 and 21, Kroll teaches a composition useful for forming a film layer comprising a thermoplastic composition comprising **at least one** thermoplastic polymer and at least one diluent or radiation responsive composition (column 1, lines 55 – 60). Kroll teaches that the thermoplastic polymer can comprise water swellable polymers, water soluble polymers, water dispersible polymers or biodegradable polymers (column 2, lines 55 – 62). Kroll teaches that the WVTR is most preferably from 1000 to 2000 g/m²/day **or higher** (column 2, lines 40 – 44), meeting Applicant's requirement of greater than 2500 g/m²/day. Kroll teaches that the film is useful in applications such as disposable articles such as disposable diapers, feminine napkins and medical devices and dressings (column 1, lines 10 – 17).

As to claims 2 – 3, Kroll teaches that the WVTR is most preferably from 1000 to 2000 g/m²/day **or higher** (column 2, lines 40 – 44), meeting Applicant's requirement of greater than 3000 and greater than 3500 g/m²/day.

As to claims 4 - 5, Kroll teaches the use of polycaprolactone and polylactic acid as the biodegradable polymer (column 6, lines 15 – 22). It should be noted that polycaprolactone and polylactic acid are aliphatic polyesters as stated on page 6, lines 1 – 20 of Applicant's Specification.

As to claim 6, Kroll teaches the use of polyvinyl alcohol as one of the thermoplastic polymers (column 5, lines 5 – 15).

As to claim 7, Kroll teaches the use of polyethylene oxide as one of the thermoplastic polymers (column 5, lines 5 – 15).

As to claim 14, Kroll teaches that the film can be about 0.8 to 2 mils (column 2, lines 19 – 22).

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As to claims 17 and 18, Kroll teaches that the film is useful in applications such as disposable articles such as disposable diapers, feminine napkins and medical devices and dressings (column 1, lines 10 – 17).

Kroll fails to teach that the film is stretched as required by claim 1 and specifically that the film is stretched 100 – 500 percent of its original length as required by claim 19.

Noda is directed to an environmentally degradable film suitable for disposable articles (Abstract). Noda teaches in Example 6 stretching the film at various percentages ranging from 0% - 400% in the cross-machine direction. As the amount of stretch in the cross-machine direction is increased, the water transmission rate will be increased to many values greater than the unstretched film (column 15, lines 55 – 67). Noda teaches

It would have been obvious to one of ordinary skill in the art at the time the invention was made to stretch the film of Kroll between 0 – 400 percent of its original length as suggested by Noda motivated by the desire to enhance water vapor transmission rate through the film (column 15, lines 55 – 67).

Kroll in view of Noda fails to teach laminating the film to a nonwoven web as required by claims 1 and 21.

Wu '937 teaches a film comprising polycaprolactone blended with polyvinyl alcohol

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(PVA) (column 2, lines 35 – 50). Wu teaches that the composite can be incrementally stretched to create a film with micropores or microvoids (column 3, lines 65 – 69 and column 4, lines 1 – 2). The microvoid formation caused breathability in the biodegradable and/or compostable thermoplastic film. The breathability allows air and moisture vapor to breathe or pass through the film. Further, the increased surface area provided by stretching the film accordingly enhances the biodegradability and/or compostability of the film (column 4, lines 1 – 10). Wu teaches that the film may be laminated to one or more nonwoven webs (column 2, lines 15 – 30) to create a laminate having a soft cloth-like feel suitable for hygiene fabrics, medical fabrics and protective ground coverings (column 2, lines 1 – 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to laminate a nonwoven web as suggested by Wu '937 to the film of Kroll in view of Noda motivated by the desire to create a soft fabric suitable for various end uses such as hygiene fabrics and medical fabrics.

As to claims 10 – 13, Kroll in view of Noda and Wu discloses the claimed invention except for that the biodegradable film comprises about 1 – 50% water soluble polymer as required by claim 10, comprises 5 – 30% water soluble polymer as required by claim 11, requires 50 – 99% biodegradable polymer as required by claim 12 and requires 70 – 95% biodegradable polymer as required by claim 13. It should be noted that the amount of water soluble polymer, amount of biodegradable polymer and amount the film is stretched are result effective variables. For example, as the amount of the water soluble polymer increases, the breathability and water sensitivity of the film increases. As the amount of biodegradable polymer increases, the

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biodegradability of the film increases. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the biodegradable film comprising about 1 – 50% water soluble polymer as required by claim 10, comprises 5 – 30% water soluble polymer as required by claim 11, requires 50 – 99% biodegradable polymer as required by claim 12, requires 70 – 95% biodegradable polymer as required by claim 13 since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the amount of biodegradable polymer, water soluble polymer and the amount the film has been stretched to create a film with optimal strength, water sensitivity and breathability.

As to claims 8 – 9 and 20, although Kroll in view of Noda and Wu does not explicitly teach the claimed elongation at break of greater than about 100% as required by claim 8, elongation at break of greater than about 200% as required by claim 9 and elongation at break of about 350% or greater as required by claim 20, it is reasonable to presume that said properties are inherent. Support for said presumption is found in the use of like materials (i.e a biodegradable film comprising a composition of a blended mixture of a biodegradable polymer and a water soluble polymer which is stretched from about 100 – 500 percent of its original length) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. In addition, the presently claimed properties of elongation at break of greater than about 100% as required by claim 8, elongation at break of greater than about 200% as required

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by claim 9 and elongation at break of about 350% or greater as required by claim 20 would obviously have been present once the Kroll in view of Noda and Wu product is provided.

Response to Arguments

6. Applicant's arguments filed July 25, 2005 have been fully considered but they are not persuasive.

Applicant argues that Wu '937 does not teach a stretched monolayer precursor film. As discussed by Applicant, Wu teaches that the stretched composite can comprise a laminate of one or more plies of a biodegradable and/or compostable film polymer and one or more plies of a biodegradable and/or compostable nonwoven web. It should be noted that the laminate can comprise a single layer or monolayer film laminated to one ply of a nonwoven web. Although Wu requires that the laminate comprising both the film(s) and nonwoven(s) is incrementally stretched, the claim language does not preclude the film and the nonwoven layers both being stretched.

Applicant argues that it would be unlikely that a skilled artisan would have been inclined or necessarily able to stretch the composite structure using the incremental stretching methodology of Wu '937 and Wu '247 in accordance with the high WVTRs of the claimed invention, since this would appear contrary to Wu '937 and Wu '247 explicit objective of retaining water impermeability. Additionally, Applicant argues that it is unclear whether the stretching techniques of Wu '937 and Wu '247 would even be able to provide a WVTR of greater than 2500 g/m²/24 hours. It should be noted that Applicant does not provide any evidence to support these arguments. In the applied prior art Kroll et al. (US 6,432,547), Kroll teaches a

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composition for forming a film which is impermeable to fluids and exhibits a water vapor transmission of at least $100 \text{ g/m}^2/\text{day}$ (see Abstract). Kroll additionally teaches that the water vapor transmission can most preferably be $1000 - 2000 \text{ g/m}^2/\text{day}$ or higher (see column 2, lines 30 – 45). Therefore, one cannot assume that a material having a high WVTR as claimed cannot also be impermeable as required by Wu '937 and Wu '247. The burden is upon the Applicant to provide evidence showing that the film of Wu '937 and Wu '247 would not be impermeable to liquids if stretched to have a WVTR as claimed by the Applicant. Furthermore, the burden is upon the Applicant to provide evidence that the stretching techniques of Wu '937 and Wu '247 cannot produce a film with Applicant's claimed WVTR.

Applicant reminded the Examiner of the Office's position regarding rejections similarly applied to claims recited stretching and elongation break limitations over Kroll in a related application. The Examiner submits that each application must be evaluated separately and, in this Examiner's opinion, the rejection may be appropriately maintained.

Applicant argues that neither Kroll nor Noda teach a biodegradable film as claimed laminated to a nonwoven web. In view of Applicant's amendments to claims 1 and 21, the Examiner has revised the previously applied rejection above to account for laminating a nonwoven web to the film.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jennifer Boyd
October 7, 2005


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